# Reducing Biological Risks to Security

## International Policy Recommendations for the Obama Administration

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While not all participants agreed with every detail of these recommendations, there is strong agreement on the broad thrust of the international policy initiatives outlined here.

# Introduction

The rapid advance and global spread of biotechnology and the life sciences promise enormous benefits for public health and opportunities for promoting sustainable economic development. At the same time, these trends are exacerbating the risk that biotechnology might accidentally, inadvertently, or deliberately be used in ways that cause harm. Because of the global diffusion of the life sciences, global approaches are needed to reduce these risks while securing the benefits of biotechnology.

Yet efforts to advance global action face significant political and economic challenges, including differences in national priorities and capabilities and concerns about policy actions that might threaten national sovereignty. In the United States, bioterrorism remains a primary concern. But in most developing countries, primary concernsare the risks to human and animal health and well-being from natural disease outbreaks exacerbated by inadequate public health and agricultural resources, capacity, and infrastructure. Developing countries do not want counter-bioterrorism initiatives to impede or divert resources from efforts to strengthen public health and agriculture.

The challenge of reducing biological risks is also complicated by the increasing importance of the private sector and academia in biotechnology and the life sciences. Engaging these non-State actors is critical, but many participants in industry and academia do not fully appreciate the potential risks associated with their work. Limited oversight and transparency heighten uncertainty about private-sector products and practices. Greater involvement, interaction and communication among these and many other stakeholders are key to effectively addressing 21$^{st}$ century biological threats. New partnerships and cooperative international security mechanisms, built on the normative and legal foundations of the Biological Weapons Convention (BWC) and the International Health Regulations 2005 (IHR 2005), must be established.

In recent years, the U.S. government has strengthened its national preparedness and response capabilities for catastrophic disease events, including bioterrorism. But it has paid inadequate attention to prevention and response measures internationally, thereby increasing our vulnerability to a significant biological event and heightening the skepticism of other countries about our commitment to either improving global public health or reducing deliberate and accidental biological risks to global security.

The Obama Administration can change course, correct this deficit, and take strong action to reduce biological risks to security. To this end, the United States should:

- Pursue multilateral efforts to establish internationally harmonized standards for pathogen and laboratory safety and security and to provide technical and financial assistance to developing countries to facilitate their adoption, sustainable implementation, and enforcement of national measures for the safety and security of biological agents;

- Pursue bilateral, regional and multilateral efforts to strengthen national criminal legislation and law enforcement capabilities for detecting, interdicting, investigating and prosecuting biological crimes, and promote international legal and technical cooperation towards these ends;

- Support efforts to strengthen the UN Secretary-General's mechanism for investigating allegations of biological weapons use and to establish a capability to investigate alleged breaches of BWC obligations if the Security Council determines that investigation is warranted;

- Pursue stronger confidence-building and other transparency measures designed to provide mutual reassurance that national biodefense and other dual-use activities comply with the BWC;

- Strengthen cooperative efforts to improve national, regional, and multinational surveillance and response capabilities with respect to outbreaks of infectious diseases, whether naturally occurring or man-made; and

- Support the development of international mechanisms that enhance the coordination and implementation of biological threat reduction policies.

To create coherence in the face of competing priorities, a careful balance must be maintained among policy attention to intentional biological threats, to accidents, and to naturally occurring infectious diseases. Although the initiatives proposed here focus primarily on deliberate, inadvertent, and accidental disease threats, they aim wherever possible to generate synergies with efforts to counter naturally occurring infectious diseases and to promote global biotechnology development. However, these initiatives will achieve only limited results if the United States does not make a serious and sustained commitment to addressing broader global public health concerns. U.S. capacity-building assistance must help recipient states meet their social and economic needs and support recipient states' ownership of their own capacity development.

In the coming years, U.S. pursuit of its bio-risk reduction objectives will take place in a world of increasing multipolarity and deepening fiscal and economic challenges. These trends and challenges make the task of achieving greater security for the United States more difficult. They also highlight the need, and provide opportunities, for our nation to renew its commitment to productive global partnerships and engagement.

## PATHOGEN AND LABORATORY SECURITY

**Recommendation 1: Pursue multilateral efforts to establish internationally harmonized standards for pathogen and laboratory safety and security and to provide technical and financial assistance to developing countries to facilitate their adoption, sustainable implementation, and enforcement of national measures for the safety and security of biological agents.**

### The Problem

Pathogen and laboratory security refers to measures for preventing the theft, diversion, or misuse of dangerous pathogens and toxins. These include measures for the physical protection, control and monitoring of dangerous biological materials; the vetting of persons with access to them; the tracking of their possession and transfer; and the oversight of high-consequence research involving them. In addition to helping prevent unauthorized access to these materials, security measures can inform national authorities about legitimate holdings and high-risk activities, help prevent dual-use research from having destructive consequences, help authorities identify suspicious or negligent activities, and enable them to impose criminal sanctions against illicit activities.

Effective biosafety measures, which are taken to prevent harm from accidental exposure to or release of biological agents, are essential for effective pathogen and laboratory security. Together, safety and security measures provide a comprehensive approach for managing and reducing risks associated with the possession, handling and use of biological agents. However, gaps and inconsistencies remain in national and multilateral systems for pathogen and laboratory safety and security. Divergent interests and priorities (e.g., bioterrorism vs. naturally occurring infectious diseases) complicate the challenge of building effective, sustainable and internationally harmonized systems.

### Review and Assessment of Current Efforts

After 9/11 and the anthrax letter attacks, the U.S. government tightened controls on access to pathogens and toxins that could significantly threaten human, animal or plant health if used as weapons. Yet, as illustrated by numerous incidents and reports in the United States, significant gaps remain in both biosafety and pathogen and laboratory security measures. The Commission on the Prevention of WMD Proliferation and Terrorism recently recommended that the U.S. government take steps to improve pathogen and laboratory safety and security both at home and abroad.

Indeed, relatively few countries have implemented strong pathogen and laboratory security and biosafety measures, even though work with dangerous pathogens and toxins is expanding rapidly. Many countries lack even basic safety and security regulations. International organizations, such as the World Health Organization (WHO), the World Organization for Animal Health (OIE) and the Organization for Economic Cooperation and Development (OECD), have issued guidelines and conducted workshops on laboratory biosafety and/or pathogen security. However, many nations lack the means to give priority to implementing and enforcing them, or simply have failed to do so. The adoption and implementation of security-related guidelines in particular remain incomplete.

Through the Defense Department's Biological Threat Reduction Program (BTRP) and the State Department's Global Threat Reduction Program (GTRP), the United States has provided financial and technical assistance to improve safety and security at biological facilities in countries of the former Soviet Union. The State Department has recently initiated similar activities in other regions through the Biosecurity Engagement Program.

However, these efforts are poorly coordinated and insufficiently resourced to reach many parts of the world, especially sub-Saharan Africa. In addition, these programs face challenges fostering ownership by recipient states of their own capacity development, as well as challenges aligning U.S. security goals with recipient states' urgent public health, agricultural and biotechnology capacity-building needs and priorities. These problems reduce program effectiveness and the likelihood of generating sustainable improvements.

Policy Recommendations

Every country that permits peaceful uses of dangerous pathogens and toxins should implement effective and legally binding measures for their safe and secure storage, handling, use, and transfer. Such measures could include:

- Readily updatable lists of pathogens and toxins subject to safety and security regulation;
- National registries of laboratories, culture collections and other facilities that possess these agents;
- Legal prohibitions on unregistered possession, handling, use and transfer of certain agents;
- Laboratory risk assessment methods to ensure that the level of security is commensurate with the level of risk;
- Provisions for risk assessment and oversight of high-consequence life sciences research;
- Training, standards and infrastructure for ensuring the physical security, safe handling, and appropriate use of dangerous materials, as well as for access control and materials monitoring and accounting;
- Personnel reliability measures, including vetting;
- Regulations for the safe and secure transport of dangerous pathogens and toxins;
- Record-keeping and reporting requirements for transfers of biological agents, applicable to both suppliers and recipients; and
- Reporting requirements and emergency response plans for safety or security breaches.

These measures will necessarily vary from country to country given the variety of dangerous pathogens and toxins, of facilities that work with them, of carriers that transport them, and of local and national conditions. However, to minimize gaps and inconsistencies among national approaches, they should be based on internationally harmonized standards and guidelines, and should apply to all facilities that hold dangerous pathogens and toxins, all scientists and other personnel who have access to them, and all transportation modes that convey them.

At home, every relevant U.S. government agency should coordinate its oversight functions for biosafety and pathogen and laboratory security. Means should be established to ensure consistent promulgation and implementation of national biosafety and pathogen and laboratory security measures.

Internationally, the United States should pursue multilateral efforts to develop internationally harmonized standards and guidelines and to promote their implementation. One approach would be for the United States to support the establishment of a multilateral Technical Working Group (TWG), under the auspices of the UN or the BWC and involving leading international scientific organizations

such as the WHO, which would develop a set of internationally harmonized security standards that complement and supplement existing biosafety guidelines.

Controls are also needed on international transfers of dangerous agents. The TWG could work with the World Customs Organization and others to develop harmonized standards and guidelines for tracking and reporting international transfers of biological agents to national authorities and for end-user verification, as well as an international system for monitoring such transfers.

Whether promoting a TWG or comparable international approach, the United States should encourage States to enact domestic legislation and implement and enforce subsidiary regulations. Positive incentives, training programs, transparency, and information exchange measures may be effective ways to provide such encouragement.

For some States, the costs of implementing pathogen and laboratory security measures and their lack of technical knowledge and infrastructure will be disincentives, and these countries will prefer to direct their limited financial and human resources towards higher national priorities. To address this problem, the United States should expand its biological threat reduction programs globally, and should align its efforts more closely with the needs, priorities, and implementation strategies of recipient nations. For example, donor-funded, partner-led efforts to help developing countries meet their IHR 2005 obligations and advance their national health needs, including greater scientific collaboration and exchange, could provide a foundation on which to strengthen biosafety and pathogen and laboratory security. The United States should also improve coordination, both across U.S. government agencies and with other donor nations, in order to achieve the most efficient use of available resources.

## LAW ENFORCEMENT

**Recommendation 2: Pursue bilateral, regional and multilateral efforts to strengthen national criminal legislation and law enforcement capabilities for detecting, interdicting, investigating and prosecuting biological crimes and promote international legal and technical cooperation towards these ends.**

### The Problem

Law enforcement officials should be authorized and able to detect, investigate, and interdict actual and planned biological crimes and terrorist attacks. They should also be able to identify, apprehend and prosecute perpetrators.

Today, however, many countries lack comprehensive criminal legislation to prohibit and assign penalties for (1) the acquisition, development, production, transfer, or use of biological agents, equipment, and means of delivery with intent to cause harm; and (2) unauthorized access to or use of laboratories or possession of critical biological agents. Crafting such legislation is complicated by the need to ensure that legitimate activities involving dangerous biological agents are permitted.

Many countries also lack sufficient capacity to collect evidence, develop early-warning systems, coordinate among relevant agencies, train law enforcement personnel, or provide necessary scientific and technological support for investigating and prosecuting biological crimes. These problems are often compounded by a general lack of investigatory and other law enforcement capabilities with respect to ordinary criminal activities. Thus, efforts to help these countries strengthen their law enforcement capabilities with respect to preventing and responding to biological crimes should also contribute to improving their overall law enforcement capabilities.

Finally, systems to ensure international cooperation in arresting, extraditing, and prosecuting persons who develop, produce or use biological weapons are also inadequate. The international community lacks agreed procedures for investigating and resolving biological crimes that have transnational implications, including procedures for gathering and analyzing evidence and for sharing information. This problem could be especially serious in connection with an ongoing series of biological attacks when prompt identification and apprehension of perpetrators would be critical.

Review and Assessment of Current Efforts

In 2004, the UN Security Council adopted Resolution 1540 (UNSCR 1540), which requires that all UN Member States (1) adopt and enforce prohibitions against non-State actors developing, acquiring, transferring, or using nuclear, chemical, or biological weapons and their means of delivery for terrorist purposes; and (2) establish domestic controls to prevent the proliferation of such weapons and their means of delivery. UNSCR 1540 established the 1540 Committee to monitor and assist State compliance. Although the mandate of the 1540 Committee was extended in May 2008, initial hopes that the resolution would spur States to take vigorous national measures to prevent biological crimes have not been fulfilled.

The United States has promoted policies to strengthen national legislation relevant to the goals of UNSCR 1540 and the BWC. The United States has also supported the Interpol Bioterrorism Prevention Program to help developing countries strengthen their national criminal legislation and to raise police awareness of biological threats through workshops, train-the-trainer programs, and response guides. However, in most countries, law enforcers remain insufficiently authorized, trained or equipped to carry out necessary tasks. Efforts to address this situation are complicated because most countries have scarce resources to confront other serious and more urgent law enforcement challenges (e.g. organized crime, illicit drug trafficking, and other forms of terrorism).

Policy Recommendations

Ideally, every nation should have strong criminal legislation against the preparation for and perpetration of biological crimes. Law enforcers should be educated about laws relevant to illicit biological activities, and about intelligence, investigative, forensic, prosecutorial, and ethics requirements for success within their country's legal framework. Law enforcers should also be provided with and trained to use equipment for the collection, preservation, analysis and interpretation of forensic evidence.

The United States should provide greater financial and technological support for national, regional, and international efforts to (1) establish strong national criminal legislation against biological crimes, (2) train police to detect illicit biological activities, (3) enhance bio-forensic methods and capabilities, and (4) build cooperative relationships and information sharing networks between law enforcement and other key sectors and agencies (e.g. regulatory, public health, scientific). Equipment for sensing, sampling, and analyzing biological materials should be offered to organizations and States that can use it effectively. U.S. assistance with respect to biological crimes should be integrated with efforts to strengthen general law enforcement capabilities in recipient nations.

The United States should promote the enhancement and make full use of the capabilities of Interpol, the 1540 Committee, and the BWC Implementation Support Unit to help strengthen national legislation and law enforcement capabilities against biological crimes. The United States should also promote effective synergies and coordination among these and other relevant entities, including the UN's Counter Terrorism Implementation Task Force and the Office of Disarmament Affairs.

Moreover, the United States should pursue, and provide assistance for, multilateral, regional and bilateral agreements, mechanisms and networks that promote international cooperation in the

investigation of suspicious biological activities and incidents. Such agreements should develop mechanisms and clarify standards for:

- Coordinating investigations;
- Collecting, analyzing and using forensic evidence;
- Sharing and releasing information;
- Protecting privacy, civil liberties, and confidential business information;
- Assessing intelligence and other relevant information;
- Effective attribution; and
- Extradition and prosecution.

## INTERNATIONAL BIOLOGICAL WEAPONS INVESTIGATIONS

**Recommendation 3: Support efforts to strengthen the UN Secretary-General's mechanism for investigating allegations of biological weapons use and to establish a capability to investigate alleged breaches of BWC obligations if the Security Council determines that an investigation is warranted.**

### The Problem

The BWC outlaws the development, production and possession of biological and toxin weapons. Under Article VI of the Convention, any State Party may request that the UN Security Council consider a complaint that another State Party is acting in breach of its BWC obligations. The ability of the Security Council to carry out investigations could facilitate the international resolution of such allegations, enhance the flexibility and policy options available to the Council, and help deter biological weapons proliferation. However, substantial political and operational challenges confound any effort to investigate alleged violations of the BWC. Moreover, there is no standing international capability for conducting such investigations impartially and professionally.

The UN Secretary-General does have the authority to investigate allegations of biological weapons *use* on his own initiative or at the request of the Security Council or a UN member State. However, the Secretary-General lacks the resources needed to rapidly field an independent, qualified, trained and equipped team of investigators. Instead, the Secretary-General must rely on a hastily-assembled team of experts provided by member states on an *ad hoc* basis. These experts are likely to have varying levels of training and expertise and no previous experience working together. In several cases where investigations have been initiated by the Secretary-General, these problems have contributed to suboptimal performance, delays in response and the conduct of investigations, and concerns about quality and bias.

### Review and Assessment of Current Efforts

In 2005, the bipartisan U.S. Task Force on the United Nations recommended establishing a new UN body that would train and administer a roster of biological weapons specialists to provide the Secretary-General and the Security Council with a standby investigation capability, and that would develop a manual to guide investigations. At the Sixth Review Conference of the BWC in 2006, States Parties invited the Security Council to utilize the Secretary-General's existing mechanism to

investigate an allegation of biological weapons use if it deems that an investigation is warranted. The States Parties also reiterated their invitation to the Security Council to "initiate any measures it considers necessary" to investigate an alleged breach of the BWC. Earlier in 2006, the UN General Assembly encouraged the Secretary-General to update the nearly 20 year-old roster of experts and laboratories available on short notice and to update the technical guidelines and procedures for investigations of alleged use. The UN updated the roster of experts in 2008, but little progress was made on updating the procedures because of the sovereignty concerns of some nations.

Policy Recommendations

The United States should undertake a high-level diplomatic initiative to build the consensus needed to (1) strengthen and regularly update the existing Secretary-General's mechanism for investigating allegations of biological weapons use; and (2) secure a Security Council commitment to consider and, if warranted, authorize the investigation of alleged breaches of the BWC.

The United States should work closely with the UN, other BWC States Parties, and Interpol to train a cadre of dedicated biological weapons investigators who are capable of investigating complaints of biological weapons use or a breach of BWC obligations. Outstanding senior and experienced personnel should be recruited to comprise an international roster of respected professionals from the law enforcement, medical, scientific, legal, intelligence and military communities. They should be trained to work together as teams and should operate under UN staff codes if called into action.

Moreover, the United States should provide support for strategic, operational and logistical planning for investigations, and for updating the operational guidelines and procedures, including procedures for collecting, sharing, safeguarding and analyzing open-source and intelligence information during the conduct of an investigation. The United States should enhance and contribute its investigative capabilities, including technical and scientific resources, and should participate in an international network of validated reference laboratories. The United States should also contribute to a UN reserve fund to support training activities and investigations.

## BIODEFENSE ACTIVITIES

**Recommendation 4: Pursue stronger confidence-building and other transparency measures designed to provide mutual reassurance that national biodefense and other dual-use activities comply with the BWC.**

The Problem

Ongoing secrecy at some biological research facilities and expanding national biodefense activities in some countries continue to raise concerns about BWC compliance. Several Russian biological research facilities remain closed to outsiders, and, although the Chinese have made tentative moves toward greater openness in recent years, Chinese intentions and activities also remain opaque. For its part, the U.S. government has expanded its biodefense efforts over the past decade, including projects that explore potential offensive applications of biological knowledge and technologies in order to guide the development of defensive countermeasures. Some allies have expressed concern that these efforts could further blur the line between permitted and prohibited activities under the BWC. Biodefense research and dual-use capabilities are also expanding in other nations.

Every nation has the right to conduct biodefense research, but uncertainties about compliance and the direction of such research threaten to undermine the prohibition on biological weapons and to undercut the trust and cooperation on which global efforts to reduce biological threats rely.

Transparency, oversight and accountability are central to generating confidence in BWC compliance and maintaining the legitimacy of biodefense and other dual-use biological research.

Review and Assessment of Current Efforts

Today, the BWC Confidence-Building Measure (CBM) process is the only formal and potentially universal mechanism for increasing the transparency of biodefense-related activities. BWC States Parties are politically but not legally bound to submit specific data about BWC-relevant activities on an annual basis. Sixty-four States Parties (40%) made a CBM submission in 2007, nearly twice the lowest level of participation, which occurred in 2003. Yet, many CBM submissions are incomplete or inaccurate. More worrisome, the CBM process is losing relevance in the face of economic, political, scientific and technological changes since the reporting guidelines were last updated in 1991.

Transparency can also be generated by activities that build cooperative relationships between people and institutions. According to a study by the U.S. National Research Council (NRC), the Defense Department's Biological Threat Reduction Program (BTRP) has contributed to "unprecedented transparency" at dozens of important and previously closed facilities in the former Soviet Union and has provided important insights into the interests and intentions of foreign scientists.

However, the long-term sustainability of these gains is in doubt. The BTRP and other threat reduction programs have largely disengaged from Russia because of concerns about continued Russian non-compliance with the BWC and lack of cooperation from Moscow. Increasing tensions between the United States and Russia in other spheres further cloud the prospects for cooperation. Yet, as the NRC study pointed out, "[t]here are considerable risks entailed in not participating in research engagement activities but instead simply remaining on the sidelines and speculating as to what may be taking place." In addition, U.S. biological threat reduction programs continue to face difficulties aligning with the scientific and public health interests of partner nations, which generally revolve around naturally occurring infectious disease threats rather than bioterrorism.

In the United States several agencies have established oversight mechanisms to ensure that the biodefense research they sponsor or conduct complies with the BWC. However, these mechanisms are uneven in scope and application; no common guidelines are available for agencies to use when assessing compliance; and there is no established process for high-level, interagency oversight of activities that raise even the most significant BWC compliance concerns. Moreover, U.S. agencies have not clearly communicated with outside audiences about their review processes, activities and intentions. In spite of these problems, the United States is at the forefront of international efforts to establish national BWC compliance oversight arrangements. Many other important nations lack comparable mechanisms, or any mechanisms at all.

Policy Recommendations

The United States should work to strengthen the BWC CBM regime by (1) promoting the use of the BWC Implementation Support Unit to provide assistance in assembling and submitting CBMs to those States Parties that request it; and (2) working with other nations to lay the groundwork for a thorough review and updating of the CBM mechanism at the BWC's Seventh Review Conference in 2011. During this review, the United States should advocate the development of new CBMs to address such issues as biological agent aerosolization activities, research that could enhance the weapons potential of biological agents, processes for BWC compliance review, and States Parties' activities to promote the education of life scientists about dual-use research and the BWC. Finally, the United States should promote the establishment of a mechanism for periodically reviewing the substance and implementation of the CBM declaration requirements.

In some cases, additional confidence-building efforts are necessary. Sustained efforts should be made to engage both Russia and China on biodefense and other dual-use issues. The United States should increase funding for biological threat reduction programs and transition them from programs of U.S.-directed assistance to programs that build true partnerships and scientific collaborations around common public health and research interests. Biological threat-reduction programs should also expand globally and, as they do, should be better aligned and integrated with the public health and life science research needs, priorities and strategies of partner nations. The United States should also promote more international biodefense partnerships and personnel exchanges, which should extend even to biological threat assessment activities.

Finally, the United States should begin to engage other nations in discussions concerning the development of common principles for national oversight and communication of biodefense research activities to ensure and demonstrate their full compliance with the BWC. The United States should also establish a mechanism for sustained high-level interagency assessment and oversight of its biodefense programs.

## INFECTIOUS DISEASE SURVEILLANCE AND RESPONSE

**Recommendation 5: Strengthen cooperative efforts to improve national, regional, and multinational surveillance and response capabilities with respect to outbreaks of infectious diseases, whether naturally occurring or man-made.**

### The Problem

Efforts to prevent the emergence of naturally occurring epidemics, laboratory accidents, or malevolent uses of microbes will not always succeed. The earlier an infectious disease event is detected, and the more robust and effective the ensuing response, the more resilient a society will be against infectious diseases. Improving surveillance and response capacities contributes to reducing biological threats, whether from natural disease outbreaks, laboratory accidents or biological weapons use.

At present, infectious disease surveillance and response capabilities at the national, regional, and international levels are fragmented, uneven, and inadequately funded and staffed. Strategies to bolster global surveillance and response capabilities have suffered from variable political interest and commitment, and from disagreements between developed and developing countries about policy priorities (e.g. bioterrorism versus naturally occurring infectious diseases) and about secure and affordable access to vaccines and other health technologies.

### Review and Assessment of Current Efforts

Efforts to strengthen surveillance and response capabilities against infectious disease threats have been underway in the United States and internationally since the emergence in the mid-1990s of fears about bioterrorism and the global crisis in emerging and re-emerging infectious diseases. Infectious disease crises have accelerated these efforts, as witnessed by the impact of the 2001 anthrax attacks in the United States, the global SARS outbreak in 2003, the international fears about the spread of extensively drug-resistant tuberculosis (XDR-TB), and the on-going concern about avian influenza and the potential for a human influenza pandemic.

The United States has initiated and/or supported efforts to strengthen national, regional, multilateral, and global surveillance and response capabilities, such as the IHR 2005, the National Biosurveillance Integration System at the Department of Homeland Security, and the WHO's Global

Outbreak Alert and Response Network. Advances in information technologies have bolstered efforts to improve national and global surveillance systems.

Despite this progress, serious problems remain. Surveillance systems remain inadequate and vulnerable to competing political and fiscal priorities. Surveillance systems for animal health and human health are inadequately coordinated and integrated, despite the threat from zoonotic diseases like SARS and avian influenza. And surveillance improvements in developing countries lag behind those of most developed countries. Meanwhile, national and global attempts to bolster response capacities are even further behind, particularly in developing countries. The imbalance between surveillance and response capabilities will be debilitating in the short- and long-term, whatever the origin of the pathogenic threat.

The IHR 2005 require all WHO Member States to develop and maintain core national surveillance and response capabilities, but plausible strategies for achieving and funding developing country compliance with these international legal obligations have not materialized. Moreover, as revealed by the controversy over Indonesia's decision not to share samples of the H5N1 influenza virus with the WHO, developing countries are becoming increasingly intolerant of approaches to global disease surveillance that mainly benefit developed countries with their greater capabilities to respond to infectious disease threats. Instead, developing countries may seek increased support for surveillance capabilities that more closely reflect their national priorities and place greater emphasis on strengthening national and local public health and health care response capabilities.

Policy Recommendations

Given the global nature of the threats posed by biological weapons and naturally occurring infectious diseases, "weak links" in surveillance networks and response systems threaten the health of all nations, as well as global cooperation. The United States must work closely with other countries and the WHO to close three critical gaps: (1) the gap between rapid progress on infectious disease surveillance and lagging improvement in response capacities; (2) the gap between surveillance capabilities in developed and developing countries; and (3) the gap between response capacities in developed and developing countries.

To address these gaps, more attention must be paid to naturally occurring infectious diseases and the common threats they pose to developed and developing nations. Many developing countries perceive the United States as interested only in protecting itself from the threats of bioterrorism and natural outbreaks of infectious disease. This perception damages prospects for achieving the kinds of improvements in surveillance and response systems that are required in today's highly interdependent world.

To enhance national, regional, and multilateral efforts to improve public health surveillance and response capabilities, the United States should:

- Deliver increased capacity-building assistance for IHR 2005 implementation, consistent with development principles stressing the importance of local ownership, priority setting, and strategy formulation;

- Realign the State Department's Biosecurity Engagement Program and other biological threat reduction programs to better support the infectious disease surveillance and response priorities of the countries with which they engage;

- Encourage stronger commitment from regional organizations for initiatives on regional improvements to infectious disease surveillance and response capacities;

- Develop a high-level initiative among leading developed and developing countries (e.g., European Union, Russia, China, India, Brazil, and South Africa) to advance coordinated efforts to ensure effective implementation of the IHR 2005 core capacity requirements for surveillance and response by the June 2012 deadline; and

- Integrate the need to improve global health surveillance and response into the National Health Security Strategy being developed pursuant to congressional legislation.

## INTERNATIONAL POLICY COORDINATION

**Recommendation 6: Support the development of international mechanisms that enhance the coordination and implementation of biological threat reduction policies.**

### The Problem

Reducing biological threats is the shared responsibility of many sectors - government (e.g., health, security, law enforcement, intelligence), scientific, and private. Numerous actors, from the local to the international, must undertake threat reduction activities, and they must do so in relative harmony if such efforts are to be broadly effective. Disparate agencies and communities will not, on their own, be able to reach across their different perspectives to harmonize and integrate their missions and activities. Yet, effective mechanisms for supporting the coordination of biological threat reduction policies and efforts globally do not currently exist. As a result, threat reduction policies and efforts lack sufficient direction, commitment and follow-up from governments and other actors. Capabilities and resources are being fragmented and strained, particularly in developing nations, without producing substantive or sustainable progress.

### Review and Assessment of Current Efforts

Approximately 30 international organizations are engaged in activities that are relevant to reducing biological threats. Each organization has a demarcated mandate and its own separate bureaucracy and agenda, and each devotes specialized expertise to carrying out distinct aspects of the biological threat reduction enterprise. But the efforts of these organizations are insufficiently coordinated to produce an optimal effort against biological threats. As former UN Secretary-General Kofi Annan noted in Uniting Against Terrorism, "[t]hese efforts are to be applauded but, unless they are brought together, their effects will be diffuse. What we need now is … [to] bring together the various stakeholders - Governments, industry, science, public health, security, the public writ large - into a common programme, built from the bottom up, to ensure that biotechnology's advances are used for the public good and that the benefits are shared equitably around the world."

### Policy Recommendations

The United States should support the establishment of a coordinating mechanism for biological threat reduction within the UN, either as a committee created by the Security Council (e.g., like the 1540 Committee) or through a joint commission created by the General Assembly (e.g., like the Disarmament Commission or International Law Commission). The UN represents the best venue for a new coordinating platform that can synchronize global strategies to reduce biological threats. It has the necessary international legitimacy for the effort to take root and prosper. It can engage the many sectors that must be involved in reducing the threat from biological agents and can encourage institutional coordination among government bodies, universities, research centers, NGOs, and

private companies. In addition, the UN is well placed to ensure that developed and developing country interests are represented in multilateral biosecurity initiatives coordinated under its auspices.

The U.S. government should support initiatives that can contribute to the establishment and growth of a UN coordinating mechanism as part of a broader effort to help improve coordination for biological threat reduction. In particular, in cooperation with its OECD partners, the United States should directly engage the private sector in discussions of the biosecurity implications, both positive and negative, of advances in biotechnology and of mechanisms for advancing global biosecurity while facilitating scientific innovation. The United States should also actively support UN efforts to convene a global forum on biotechnology that brings together governments, academia, civil society and the private sector, as proposed by former UN Secretary-General Kofi Annan in 2006 and now being developed in a slightly different form by the current Secretary-General, Ban-Ki Moon. Recently, the Commission on the Prevention of WMD Proliferation and Terrorism called for the establishment of formal and informal mechanisms for sustained dialogue among all stakeholders. An essential component of these efforts should be to identify innovative, flexible, and voluntary approaches to complement and supplement regulatory and legislative approaches. Finally, the United States should also strongly support efforts to enhance coordination of biological threat reduction efforts through the BWC and the IHR 2005.